

General Responses to EPA's Non-Directive Comment Key Issues on the Baseline Human Health  
Risk Assessment  
November 18, 2010

Issue Category	BHHRA Non-Directive Comments	General Response	Resolution
Change to Exposure Scenarios	General 10, General 12(ii), 10, 45, 52, 163	<p>Exposure scenarios for the BHHRA and the approach for evaluating those scenarios were previously identified in the EPA approved (approval date of July 6, 2006) "Technical Memorandum for Human Health Risk Assessment: Exposure Point Concentration Calculation Approach and Summary of Exposure Factors (dated April 21, 2006)". In addition, the exposure scenarios were evaluated in the Round 2 Comprehensive Report without comment from EPA, or the comment was addressed in the draft BHHRA. Changes to these exposure scenarios are now being requested by EPA without information on why a change is warranted at this time. The following changes are being requested in EPA's comments:</p> <ul style="list-style-type: none"> <li>• Evaluation of ingestion of human milk by infants for all receptors (this previously was identified as an exposure pathway for fish consumers only)</li> <li>• Combining adult and child scenarios</li> <li>• Addition of beach user exposure to groundwater seeps</li> <li>• Use of the 95% UCL/maximum concentration for all exposure scenarios</li> <li>• New child receptors: child fisher, child tribal fisher, and child consumer (it is not clear whether these are actually requests for new receptors or just a misstatement about the receptors evaluated in the BHHRA)</li> </ul>	<p>Based on the October 15 meeting, EPA will require that the evaluation of ingestion of human milk by infants be included for all receptors where PCBs, DDx, and/or dioxins are COPCs.</p> <p>EPA will require that the adult and child scenarios be combined. Per discussion between Elizabeth Allen, Mike Poulsen, and Laura Kennedy and a subsequent email from Elizabeth Allen on October 26, the child and adult receptors can be presented separately, as is done in the draft BHHRA. An additional scenario for combined child/adult exposures would be included as well as a separate table for those scenarios that currently include both child and adult receptors (the scenario would add the child risk to the adult risk, which would be modified for 24 years versus the 30 years used in the adult only scenario). For cPAHs, early life exposures using age-dependent adjustment factors will be included in both the child (0-6 years) and the combined child/adult scenarios. The adult only scenarios will not be changed. The PRGs used in the FS will continue to be based on adult exposure scenarios and not on the combined child/adult scenarios because the PRGs based on adult exposures are considered protective of human health. EPA will commit to the use of PRGs based on adult exposure scenarios in writing.</p> <p>EPA will not require the addition of beach</p>

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			user exposure to groundwater seeps, use of the 95% UCL/maximum concentration for all exposure scenarios, or new child receptors.
Change in Dataset	32, 38, 39, 40, 54, 194	<p>The data sets used in the draft BHHRA were based on prior discussions and agreements with EPA, as documented in the Issue Resolution table for the Round 2 Comprehensive Report and the Meeting Summary Memo dated June 9, 2008. EPA is now requesting changes to those data sets. To include additional data and/or modify the data evaluated in the BHHRA would be a significant effort. The following changes are being requested in EPA's comments:</p> <ul style="list-style-type: none"> <li>• Inclusion of data outside of the Study Area in identifying COPCs</li> <li>• Additional surface water data for transient and recreational beach user exposures</li> </ul>	EPA will not require the changes to the data sets used in the BHHRA that were requested in the identified non-directive comments.

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Clarification Needed	10, 110, 120, 159, 187	Clarification is needed from EPA.	<p>EPA provided the following clarifications:</p> <p>#10 – The parenthetical note in EPA's comment can be deleted.</p> <p>#110 – The revised BHHRA should provide some qualitative or quantitative information regarding the portion of the life cycle of anadromous fish that would be spent in Portland Harbor. Information (qualitative or quantitative) about PCB concentrations in the Queets, Quinault, and Chehalis rivers relative to Portland Harbor should be presented, if available.</p> <p>#120 and #187 – Prior to eliminating a chemical as a COC based on N-qualified data, the sediment data for the tissue COCs should be evaluated. If the N-qualified chemicals in tissue of small home range species (i.e., smallmouth bass, clams, and crayfish) result in a risk greater than <math>10^{-6}</math> and are positively identified in sediment within the same exposure area, the chemical should be identified as a chemical potentially posing unacceptable risk.</p> <p>#159 – The revised BHHRA should provide additional analysis of the Round 1 and Round 3 data to confirm that the use of the Round 3 data does not bias results.</p>

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Summary of Risk Results	76, 78, 92, 97	EPA requested that a summary discussion be included at the end of the risk characterization section for each exposure medium evaluated in the BHHRA. The LWG proposes that the summary discussion should identify those chemicals with cancer risks greater than $10^{-6}$ , $10^{-5}$ , and $10^{-4}$ and hazard quotients greater than 1.	EPA agrees with the response.
Carcinogenic PAHs	164	The draft BHHRA included risk estimates for both individual and total carcinogenic PAHs. The LWG agrees to add discussion of the risk results for total carcinogenic PAHs in the revised BHHRA, but does not agree that the risk results for total carcinogenic PAHs should be presented instead of individual PAHs.	EPA agrees with the response.
Additional Language, Information, and/or Analyses Will Be Provided	65, 90, 100, 160, 167, 177, 185, 195, 196, 197, 199, 201, 206, 207, 210, 211	The LWG accepts the comment and will include additional language, information, and/or analyses in the revised BHHRA in addressing the comment.	EPA agrees with the response.

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Probabilistic Risk Assessment (PRA)	107	The LWG agrees that the tiered approach to PRA begins with a point estimate risk assessment, which is what was done in the BHHRA. However, RAGS Volume 3 Part A clearly states "In the point estimate approach, parameter uncertainty is addressed in a qualitative manner for most variables". This is true for the BHHRA, as shown in Table 7-1 where the range of uncertainty could not be quantified for many variables. The advantages to a probabilistic risk assessment (PRA) are stated in RAGS Volume 3 Part 3 "In general, compared to a point estimate risk assessment, a PRA based on the same state of knowledge may offer a more complete characterization of variability in risk, can provide a quantitative evaluation of uncertainty, and may provide a number of advantages in assessing if and how to proceed to higher levels of analysis". The LWG believes it is important to acknowledge the limitations of the uncertainty assessment that was included in the BHHRA.	The text will be revised to indicate that a quantitative evaluation of uncertainty is included in the BHHRA.
Changes to Text			

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Use of the Term "Conservative"	1, 5, 175	<p>The use of the term "conservative" is consistent with EPA guidance. For example, RAGS Part A (page 6-5) states that, "The intent of the RME is to estimate a <i>conservative</i> exposure case (i.e., well above the average case) that is still within the range of possible exposures", and the EPA 2002 guidance Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites states that "the exposure point concentration (EPC) is a <i>conservative</i> estimate of the average chemical concentration in an environmental medium"</p> <p>No changes to the BHHRA are proposed by the LWG in response to these comments.</p>	Overall, EPA agrees with the response. However, where the term "conservative" is used in combination with "health-protective", EPA requests that one of the terms be used.
Modification to Suggested Language	2, 3, 6, 50, 71, 145	EPA provided suggested revisions to the text of the BHHRA. The LWG proposes modifications to the suggested language for purposes of clarity and/or consistency.	EPA agrees with the response.
Description of RME Exposure Point Concentration	20, 52, 186	The draft BHHRA used the phrase "95% Upper confidence limit (UCL) or Maximum" when referring to the exposure scenario based on those exposure point concentrations (EPCs). EPA has requested that the term RME exposure be used instead. However, the exposure scenario involves multiple ingestion rates, so it is not a single "RME exposure". The LWG proposes using RME EPCs in the revised BHHRA to characterize the exposure scenario. The exposure point concentration summary tables will continue to present the basis of individual EPCs as either a UCL or a maximum.	The EPCs will be described in a factual manner in the BHHRA (i.e., the EPC will be identified as the mean, 95% UCL, or maximum). The terms RME and CT will not be used in reference to the EPCs.
Risk Management Recommendations	General 9	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.

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Use of COCs in the FS and Beyond	General 7, General 9, 29, 103, 188	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.
ARAR Evaluation in the BHHRA	General 7, 4, 8, 25, 27, 29, 31, 37, 40, 84, 118, 189, 192	This issue was addressed in the responses to EPA's Directive Comments.	Per resolution of the RI comments, the screening of surface water and transition zone water data, which previously had been included in Section 6 of the draft BHHRA, will be moved to the RI Report.
Risk Driver Section in the BHHRA	General 7, 31	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.
Changes to Text			
Deletion of Factual Statements and Comments on Remedy	7, 15, 16, 17, 21, 28, 58, 66, 74, 127, 158, 169, 183, 184, 208	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.
Deletion of EPA Direction	11, 28	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.
Description of Drinking Water Scenario		This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.
Characterization of Ingestion Rates	137, 139, 146, 178, 200	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.
Deletion of Language Regarding Compounding of Conservative Assumptions	22, 81, 87, 89, 106, 175	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.
Clam Consumption Scenario	General 2, 51, 182	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.
Regional Tissue Concentrations	General 5, 23, 95, 168	This issue was addressed in the responses to EPA's Directive Comments.	EPA agrees with the response.

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Agree	General 3, General 11, General 12(i), 9, 13, 18, 24, 33, 35, 47, 53, 55, 57, 59, 60, 61, 62, 67, 69, 70, 73, 77, 79, 80, 82, 86, 88, 91, 99, 104, 111, 112, 113, 114, 115, 116, 117, 119, 122, 123, 124, 129, 130, 131, 134, 135, 143, 144, 152, 153, 154, 155, 156, 157, 161, 165, 166, 172, 176, 179, 180, 181, 190, 202, 203, 204, 205, 209	The BHHRA will be revised consistent with the comment.	EPA agrees with the response.
Other	19, 34, 42, 46, 72, 121	While the LWG believes that the language in the draft BHHRA is accurate and consistent with risk assessment guidance and disagrees that the changes requested in these comments are needed, the BHHRA will be revised per these comments.	EPA agrees with the response.



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Inclusion of the PBDE fish tissue data in the BHHRA	Email from Chip Humphrey on 11/4/10 (not included in EPA's original comments on the draft BHHRA)	<p>The LWG and EPA had previously agreed to a data lockdown date of June 2008 for the BHHRA. EPA's comments on the draft BHHRA in December 2009 and July 2010 did not request the inclusion of the PBDE data.</p> <p>PBDEs were not included as an analyte in Round 3 per an agreement with EPA. The Round 3 fish tissue were subsequently provided to EPA for analysis of PBDEs with the understanding that the tissue were being used to assist in analytical method development and the data would not be included in the Portland Harbor RI/FS.</p> <p>The LWG disagrees with including the PBDE fish tissue data in the revised BHHRA based on prior agreements with EPA.</p>	